IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CELSIS IN VITRO, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 10 C 4053
	)	
CELLZDIRECT, INC., a Delaware Corporation and wholly-owned subsidiary of **INVITROGEN CORPORATION**; and **INVITROGEN CORPORATION**, a Delaware Corporation,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Defendants CellzDirect, Inc. and Invitrogen Corp. (hereafter collectivized as "LTC," the corporation that has succeeded to their interests) bring a motion for summary judgment of patent invalidity under 35 U.S.C. §§ 101 and 112 (Dkt. 335).[1] Also pending is LTC's Motion To Limit Damages to a Reasonable Royalty on LTC's Accused Sales (Dkt. 337). Because this Court finds the patent at issue invalid under Section 101, LTC's Dkt. 335 motion is granted and its second Dkt. 337 motion is consequently denied as moot.

Standard of Review

Every Rule 56 movant bears the burden of establishing the absence of any genuine issue of material fact (Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)).[2] For that purpose

[1] All further references to Title 35's provisions will simply take the form "Section --," omitting the prefatory "35 U.S.C. §."

[2] At the summary judgment stage, of course, Celsis need not "establish" or "show" or "prove" anything to defeat LTC's motion, but must merely demonstrate that a genuine issue of

(continued)

courts consider the evidentiary record in the light most favorable to nonmovants and draw all reasonable inferences in their favor (Lesch v. Crown Cork & Seal Co., 282 F.3d 467, 471 (7th Cir.2002)). But a nonmovant must produce more than "a mere scintilla of evidence" to support the position that a genuine issue of material fact exists (Wheeler v. Lawson, 539 F.3d 629, 634 (7th Cir.2008)) and "must come forward with specific facts demonstrating that there is a genuine issue for trial" (id.). Ultimately summary judgment is warranted only if a reasonable jury could not return a verdict for the nonmovant (Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). What follows is a summary of the facts,[3] viewed in the light most favorable to nonmovant Celsis.

Whether a patent is valid under either Section 101 or Section 112 is a question of law (Fort Properties, Inc. v. Am. Master Lease LLC, 671 F.3d 1317, 1320 (Fed. Cir. 2012) as to Section 101 and Microprocessor Enhancement Corp. v. Texas Instruments Inc., 520 F.3d 1367, 1374 (Fed. Cir. 2008) as to Section 112). And because there is a statutory presumption of patent validity, LTC must prove invalidity by clear and convincing evidence (Trimed, Inc. v. Stryker Corp., 608 F.3d 1333, 1340 (Fed. Cir. 2010)), at least with respect to Section 112. Although a recent concurring opinion in Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709, 720-21 (Fed. Cir.

(footnote continued)
material fact exists. This opinion employs the quoted terms only because the cited cases use that terminology, but it imposes on Celsis the lesser burden described earlier in this footnote.

[3] This District Court's LR 56.1, adopted to implement Rule 56, requires parties to submit evidentiary statements and responses to such statements to highlight which facts are disputed and which facts are agreed upon. This opinion cites to LTC's LR 56.1 statement as "LTC St. ¶ ," to Celsis' LR 56.1 statement as "C. St. ¶" and to Celsis' response to LTC's LR 56.1 statement as "C. Resp. ¶ --" (oddly, LTC has chosen not to file any response to Celsis' LR 56.1 statement). Where a party's response does not provide a different version of the facts than the original statement, this opinion cites only that original statement.

2014) has suggested that no such presumption attaches to patent eligibility -- and hence to patent validity -- under Section 101, this opinion need not pause to consider that possibility, for the well-settled facts compel a finding of invalidity under Section 101 regardless of which standard this Court applies.

Facts

United States Patent No. 7,604,929 ("the '929 Patent," LTC St. Ex. A) protects several variants on a claimed process for cryogenically freezing hepatocytes (a type of liver cell). Hepatocytes are useful for a variety of testing, diagnostic and treatment purposes (id. at col. 5 ll. 26-27), but before Celsis' innovation there were significant problems with using hepatocytes for those purposes (id. at col. 2 l. 22 to col. 3 l. 67). First, hepatocytes have a short lifespan, and their supply is inconsistent because it is dependent upon the availability of liver cells (id. at col. 2 ll. 30-32). Moreover, to test drugs accurately researchers prefer to use pools of hepatocytes from many different liver donors (id. at col. 3 ll. 33-49). But until Celsis's contribution, pooling hepatocytes from different donors was difficult due to the erratic supply and short lifespan of the cells (id. at col. 3 ll. 49-52).

Accordingly scientists sought ways to cryopreserve hepatocytes for later use (id. at col. 2 ll. 36-40), but both scientists and researchers found that cryopreservation significantly decreased cell viability (id. at col. 3 ll. 5-8). Prevailing wisdom therefore taught that cells could be frozen only once and then had to be used or discarded (LTC St. Ex. B ["Hardy Dep."] 129:2-129:6). That severely limited the creation of pooled hepatocyte products ('929 Patent col. 3 ll. 30 to col. 4 ll. 6).

Essentially the method taught in the '929 Patent shows that cells can be frozen and refrozen without losing significant cell viability, so that pooled hepatocyte products are far more

readily attained ('929 Patent col. 3 l. 61 to col. 4 l. 6). That process can be summarized as (1) thawing previously frozen cells, (2) separating nonviable cells from viable ones using "density gradient fractionation (especially Percoll density centrifugation)" and (3) refreezing the cells (id. at col. 4 ll. 38-50). With nonviable cells separated out, the resulting cell preparation contains a higher concentration of viable cells that can be subjected to repeated cryopreservation and thawing for drug testing and other purposes (C. Resp. ¶¶ 14-16; '929 Patent col. 9 l. 61 to col. 10 l. 67). Co-inventor James Hardy stated that the enhanced viability of the solution is attributable to a change in ratios: Reducing the raw number of nonviable cells in the solution necessarily increases the ratio of viable cells to overall cells in the solution. Hardy could not confirm that the process improved the health of any one individual viable cell (C. Resp. ¶¶ 14-16), though he did note that dead and dying cells can release harmful substances into cell solutions, so that removing nonviable cells benefits the population of viable cells (C. Resp. Ex. 37 49:25-50:6).

Here is the relevant language of Claim 1 ('929 Patent at col. 19 l. 55 to col. 20 l. 20), which is also representative of the other claims at issue:

> 1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes, being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:
>
> (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes,
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> (B) recovering the separated viable hepatocytes, and
>
> (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

As for the process involved in twice cryopreserving hepatocytes, it duplicated the technique used for single cryopreservation: subjecting the cells to density gradient fractionation (to sort out the viable from the nonviable cells) and then freezing them (Hardy Dep. 129:18-130:6; LTC St. ¶¶ 8-12).

Armed with the discovery that cells were capable of being twice frozen, Celsis built on that prior art method by repeating it. As Hardy himself admitted in his deposition, the critical advance was the discovery that cells could be frozen more than once and still retain viability ((Hardy Dep.. 127:9-131:21) (emphasis added)):

> A: My recollection, I haven't thought about this in awhile, but I think initially we just proved that you could twice freeze the cells and still have viable cells. And then we added Percoll, later, because we wanted the viable cell count to be higher, you know, what our standard specification was above 70 percent when they were thawed, because we saw ad- -- you know, a loss somewhere.
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> Q: And you knew from prior experience that if you had a -- the -- that from freezing cells that you were going to get some loss?
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> A: We were going to get some loss.
>
> Q: So you wanted to bump the number up before you froze it?
>
> A: Froze it again.
>
> Q: And the common procedure that you had known from the time you started with the company for bumping up the viability of hepatocyte cells is a Percoll centrifugation; correct?
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> A: Mm-hmm. Mm-hmm.
>
> Q: Okay.
>
> A: Yes.
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> Q: That's why you did it, and you got the outcome that you expected that you would get; correct?

A: The unexpected outcome was that you would get any activity of cytochromes at all on a fro- -- twice frozen cell, so that was the unexpected outcome, it would be expected if you would have viable cells, if they perform the way that they're supposed to, the unexpected outcome was that cells twice frozen behaved like cells that were once frozen.

Q: Behaved in terms of their enzyme operation; correct?

A: The metabolic activities as we measured them, yes.

Q: Okay. But you weren't surprised that you ended up with viable cells?

A: No, we were very surprised . . .
The industry taught me that you can only freeze them once, then they were no longer any good, that's what I learned from Paul Silber, who was the expert in hepatocytes, and -- and the other literature, that you can only freeze them one time. . .

Q: So what you -- what you did was you took cells that had been made -- had been isolated from the liver, and run through a Percoll centrifugation, and then frozen with the typical cryopreservation methodology, you took those cells now as your starting point instead of starting with a fresh liver, and you repeated the exact same process that had been used before in terms of cleaning up the cells and increasing their viability through a Percoll, losing 70 percent, 30 -- you know, 50 to 70 percent of the cells in the process, and running the same cryopreservation technique and ended up with product that got acceptable viability; correct?

A: Yes. . .

Q: Now, the process by which [you increased the percentage of cell viability] . . . there's nothing in that process that brings the cells back to life, what happens is you end up essentially playing with the denominator; isn't that true? You eliminate 50 to 70 percent of the cells that are in there and then that gets you a -- a higher viability; isn't that right?

A: Yes. You separate the non-viable cells from the viable cells.

All of the remaining claims in the '929 Patent are variants on that process but go on to specify that Percoll be used for density gradient fractionation (Claim 2), that the hepatocytes are selected from a specified group of mammals including humans (Claim 3) or are human (Claim 4), that 80% of the hepatocytes of the resulting preparation are viable (Claim 9) and

constitute a "pooled preparation of hepatocytes of multiple sources" (Claim 5) that are either pooled according to gender, race or state of health (Claims 6 and 11) or have a specific type or level of some type of metabolic activity (Claims 7 and 8) (LTC St. ¶ 18). It is undisputed that a determination that Claim 1 is invalid dooms all of those dependent claims.

It is important to note that the '929 Patent specifies that as a result of the patented method the resulting cell preparation should demonstrate at least 70% or 80% viability, with the patent specifying that scientists should measure viability using the "Trypan Blue exclusion" method (LTC St. ¶ 21). That test is known to yield variable measurements, though the parties dispute precisely how variable: LTC asserts the variability is about 50%, while Celsis asserts that it is 15% or less (C. Resp. ¶¶ 22-24). In any case, the Trypan Blue exclusion method was the standard industry test: It was used by many if not most customers, and LTC itself uses that method to measure viability (C. St. ¶¶ 1-3). Although there is an alternative and less variable method of testing hepatocyte viability (using a Guava Counter), Celsis claims that method is impractical for hepatocyte testing, so that the Trypan Blue exclusion method was the best measurement technique for the industry (C. St. ¶ 5; Dryden Decl. ¶ 17).

Procedural Posture

Celsis filed this action for infringement of its '929 Patent in June 2010, and this litigation has since subjected the patent's validity and scope to repeated examination. Initially this Court determined that Celsis had a likelihood of success on the merits when it granted Celsis' motion for a preliminary injunction back in September 2010, a decision that the Federal Circuit then affirmed on January 9, 2012 (664 F.3d 922, 924, 926 (Fed. Cir. 2012)). Next an ex parte reexamination by the Patent and Trademark Office ("PTO") separately reconfirmed the '929

Patent's validity (though it canceled one claim not at issue here) on February 28, 2012 (Ex. B to Strom Decl.).

LTC has since engineered around the patent to create pooled hepatocyte products using a newly developed elutriation process that this Court ultimately determined did not infringe the '929 Patent (21 F. Supp. 3d 960, 962-63 (N.D. Ill. 2014)). That ultimate holding reconfirmed this Court's March 24, 2011 opinion (995 F.2d 855) that had reached the same conclusion after another several-day evidentiary hearing and had therefore rejected Celsis' effort to obtain a second preliminary injunction, this time targeting LTC's method as an asserted infringement of the '929 Patent. And that 2011 determination by this Court was also affirmed by the Federal Circuit on October 21, 2011, this time in a per curiam opinion that adopted this Court's reasoning:

> After full de novo review of the record, the parties' briefs, and counsels' arguments, and for the reasons articulated in the district court's decision, we agree with, and thus adopt, the district court's construction of "density gradient fractionation" and without requiring a density gradient fractionation step after thawing the hepatocytes for a second time.[2] In light of these claim constructions, the district court did not abuse its discretion in concluding that a showing of literal infringement is not likely.
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> [2] We find that the district court carefully considered the language of the claims, the specification and prosecution history, and the testimony of the parties' witnesses in reaching its conclusions regarding the proper construction of the claims and, thus, remained true to our guidance in Phillips v. AWH Corp., 415 F.3d 1303, 1313-19 (Fed. Cir. 2005) (en banc).

But the abundance of opinions (both published and unpublished) and of other rulings during the active course of this litigation (which as of this writing has spawned no fewer than 428 docket entries at the District Court level, encompassing both the litigants' filings and those court actions) has never called upon either this Court or the Federal Circuit to address the issues

or analysis that are now before this Court under the stimulus of the Supreme Court's more recent and more intensive analysis of some fundamental patent law principles and the Federal Circuit's application of those principles.[4]

Most recently, in an effort to narrow the issues in the litigation, the parties have stipulated that if the '929 Patent is deemed valid, LTC infringed at least one of the patent's claims when it manufactured certain lots (Joint Stipulation, ECF No. 418). Thus what are now pending for decision are two motions by LTC -- one challenging the validity of the patent and a second seeking to limit any damages to which Celsis is entitled

Patent Validity Under Section 101

LTC argues that the '929 patent is invalid under Section 101 because it lacks a sufficiently inventive step to constitute patentable subject matter. Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent." Excepted from patentability, however, are "laws of nature, physical phenomena, and abstract ideas" (Bilski v. Kappos, 561 U.S. 593, 601 (2010), quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)). Patent law makes a conscious choice not to "inhibit further discovery by improperly tying up the future use of these building blocks of human ingenuity" (Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014) (internal quotation marks omitted)).

[4] As the ensuing text reflects, it is the Supreme Court's in-depth analysis in the 2012 decision in the Mayo case and the 2014 decision in the Alice case (both of those are unanimous decisions) that provides the road map for any determination of the validity of a process patent whose springboard is some law of nature -- and, of course, neither of those cases had been decided when this Court rendered its 2010 decision finding the '929 Patent valid en route to its grant of a preliminary injunction in Celsis' favor and when the Federal Circuit issued its opinion at the very beginning of 2012 affirming that decision.

While distinguishing between patentable application and unpatentable principle makes good sense in the abstract, drawing that line has proved far more difficult for the courts, especially when it comes to process patents (see Parker v. Flook, 437 U.S. 584, 589 (1978), and more recently see also, e.g., Diamond v. Diehr, 450 U.S. 175 (1981); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Alice, cited above; Univ. of Utah Research Found. v. Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014)). Because a patentable process by definition yields a prescribed result, it functions in some sense as a "law" -- the law being that steps 1 through "n" always yield specified outcome "x." So deciding whether a procedure is one deserving patent protection, or whether it is effectively locking up something that should instead remain free for all to use, is a slippery slope. And precisely because, on some level, "all inventions . . . embody, use, reflect, rest upon, or apply" unpatentable subject matter, the Supreme Court has repeatedly cautioned courts to "tread carefully in construing this exclusionary principle lest it swallow all of patent law" (Alice, 134 S. Ct. at 2354).

Recent Supreme Court decisions Mayo and Alice have shed new light on Section 101 patent validity. Mayo laid the groundwork for the precise two-part test articulated in Alice, 134 S. Ct. at 2355: First a court must "determine whether the claims at issue are directed to one of those patent-ineligible concepts."[5] If so, the court must then proceed to the second step and inquire "[w]hat else is in there in the claims before us?" (id.) At that point the court must "consider the elements of each claim both individually and as an ordered combination to

[5] Because that and all of the other quotations in this and the next paragraphs of the text were drawn from Mayo in the Alice opinion, this opinion will speak (for example) of the "Mayo-Alice step 1" (just as in a different context this Court customarily refers to the "Twombly-Iqbal canon").

determine whether the additional elements transform the nature of the claim into a patent-eligible application" (id., internal quotation marks omitted).

That second step has been characterized in Alice, id. (emphasis in original and internal quotation marks omitted) as the "search for an inventive concept -- i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." Though the caselaw identifying what constitutes an "inventive concept" is still young, as is made clear by the preceding language, the core concern motivating that second step is one of preemption.

Of course "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" (Mayo, 132 S. Ct. at 1294 (emphasis in original)). There the Supreme Court invalidated a process patent for calibrating drug dosages, where the process basically consisted of nothing more than administering a drug to patients measuring the concentration of relevant metabolites in those patients and then adjusting drug dosage up or down based upon how those metabolite concentrations correlate with drug levels (id. at 1295). Effectively the patent claimed ownership of a natural law -- the natural law being how metabolite concentrations correlated with drug dosages -- while each of the remaining "steps" in the process was necessary to apply that law (id. at 1297-98). So even though drafted as a process, the patent was really nothing more than a statement of a law of nature and an instruction to apply it (id. at 1298).

Importantly, patent law's prohibition on unpatentable subject matter cannot be circumvented by simply adding insignificant postsolution activity or by limiting the use of a formula to a specific technological environment (Mayo, 132 S. Ct. at 1294). Similarly, the addition of "well-understood, routine, conventional activity already engaged in by the scientific

community" is insufficient to transform an ineligible concept into patentable subject matter (id. at 1298). At the same time, the combination of routine steps may well yield a process that on the whole warrants patent protection (see Diamond v. Diehr, 450 U.S. 175, 188 (1981)).

Two Supreme Court cases, Parker and Diamond v. Diehr, are often contrasted to illustrate the distinction between patentable and unpatentable subject matter. Parker, 437 U.S. at 594 found a method for calculating alarm limit values unpatentable where the method consisted of three steps: measurement of different variables, calculation of a new limit by plugging those measurements into a formula and adjustment of the actual alarm limit based on the updated calculations (id. at 585). Though the patent did not preempt every single application of the formula (id. at 586), nothing about the process other than the unpatentable mathematical algorithm was new or useful (id.at 591).

Shortly thereafter in a case involving a similar set of facts, Diamond v. Diehr reasoned to the contrary. At issue there was a process for curing rubber that involved use of a long-known formula, the Arrhenius equation, to calculate the appropriate cure time (450 U.S. at 177-79, 192-93). As in Parker, the patented method involved just a few simple steps: installing rubber in a press, closing the mold, continuously measuring the temperature inside the mold, feeding the measured temperature information to a computer to recalculate an updated cure time and automatically opening the press at the proper time (id. at 187). Nonetheless the Supreme Court upheld the patent. In contrast to Parker, absent from the facts in Diamond v. Diehr was any suggestion that "all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional" -- instead the process was "an inventive application" of an otherwise unpatentable formula (Mayo, 132 S. Ct. at 1299). Thus the patentees did not "seek to pre-empt the use of [the] equation" but sought "only to foreclose from

others the use of that equation in conjunction with all of the other steps in their claimed process" (id.).

LTC argues that the '929 Patent is invalid because the claims (1) are directed toward unpatentable subject matter and (2) fail to incorporate any inventive concept. This Court agrees.

Applying Mayo-Alice step 1, this Court concludes that the patent is directed to an ineligible law of nature: the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles.[6] Though the parties cite limited caselaw detailing the meaning of "directed to" patent-ineligible subject matter, the PTO recently issued its 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 C.F.R. 74622 (Dec. 16, 2014), currently subject to public comment, that defines Alice step 1 as requiring that a law of nature, natural phenomenon or abstract idea be "recited (*i.e.*, set forth or described) in the claim." In this instance Claim 1 of the '929 Patent claims "a method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes, being capable of being frozen and thawed at least two times," and the claimed method then outlines a process for freezing the cells twice. Clearly, therefore, the patent recites the natural law that certain hepatocytes are capable of being frozen and thawed more than once. Each of the other claims is dependent on that method and so also incorporates the same recitation.

Applying Mayo-Alice step 2, this Court further agrees that the patented process lacks the requisite inventive concept. One of the inventors, James Hardy, said that "the unexpected

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[6] LTC further argues that the patent is directed toward "natural phenomena" -- hepatocytes. However, because the Court finds that the patent is directed toward a patent-ineligible law of nature, this opinion does not further address whether the process patent is also directed toward "natural phenomena." It likewise need not treat with the parties' dispute as to any continued applicability of the hoary decision in Funk Brothers Seed Co. v. Kalo Innoculant Co., 333 U.S. 127 (1948).

outcome was that cells twice frozen behaved like cells that were once frozen" -- unquestionably a natural characteristic of the hepatocytes, though no one may have remarked it before -- and it is undisputed that upon making that discovery Hardy reapplied a well-understood freezing process.

Celsis argues that repetition of that already-well-established process itself constitutes the requisite inventive concept because prior art taught away from multiple freezings. But in determining whether the process warrants patent protection, we ask "what else" is in the patent beyond the patent-ineligible concept. Here the answer is not much. This patent amounts to a straightforward application of the truth that hepatocytes are inherently capable of surviving multiple freeze-thaw cycles.[7] In light of that determination this Court need not separately analyze whether the process meets the "machine-or-transformation" test, which is an "important and useful clue to patentability" but does not "trump[ ] the law of nature exclusion" (Mayo, 132 S. Ct. at 1303 (emphasis in original and internal quotation marks omitted)).

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[7] At the District Court level Ameritox, Ltd. v. Milennium Health, L.L.C., 13-CV-832-wmc, 2015 U.S. Dist. LEXIS 19665 (W.D. Wis. Feb. 18, 2015) has stated that "if inventors engage in activities that run counter to scientific thought, those activities can hardly be considered conventional under § 101." Even putting to one side the truism that, as our Court of Appeals regularly (and properly) reminds us, District Court opinions carry no precedential weight, that case and the context for the court's decision were factually very different from the case at hand. Ameritox, id. at *18-24, *58 upheld a patent for a method of urine testing that improved the medical community's ability to monitor a patient's compliance with prescribed treatment regimens. That method involved normalizing a patient's urine sample by determining the metabolite/creatinine ratio and then comparing the normalized test results to a set of known normative data collected from other patients who were adherent to the proper treatment regimen (id. at *18-19). Thus the process as a whole satisfied Mayo-Alice step 2 because it creatively marshaled techniques that no scientist would have thought to apply to the particular field at the time. No prior art reference suggested both normalizing creatinine levels and comparing one patient's normalized data to that of other individuals to monitor treatment compliance -- and prior art taught that creatinine normalization was unreliable and that blood testing was preferable to urine testing (id. at *78). Here by contrast the combination of steps in the '929 Patent directly follows from the discovery of a law of nature: that hepatocytes are capable of surviving multiple freeze-thaw cycles -- and the patent directs the employment of methods that were routinely used in the prior art for precisely the same purpose of cryogenization to preserve such cells.

It is true that Diamond v. Diehr cautioned against dissecting claims into their constituent elements and has therefore instructed courts to construe claims as a whole. At the same time, Alice and Mayo demand that courts look beyond the natural law itself and clearly dictate that conventional steps, or the addition of insignificant postsolution activity, are insufficient to transform the unpatentable into the patentable. Here the process outlined for the second freezing is postsolution activity, implemented with entirely conventional methods.

What has been said to this point has taken care not to trench on Sections 102 and 103, which govern novelty and nonobviousness. Those sections are concerned with whether an invention is novel or nonobvious in light of the prior art -- and as Mayo, 132 S. Ct. at 1304 remarked, "§§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections."

Because claim 1 fails under the Mayo-Alice test, the other claims -- which the parties agree simply add well-known and conventional concepts -- also fail. Indeed, neither party has addressed those claims separately in its briefing.

Finally it is worth noting that this case is somewhat unique in that, although the '929 Patent lacks an inventive concept, it is more narrowly drawn than the patents at issue in Mayo and Alice because it does not lock up the natural law in its entirety. As stated earlier, LTC has already managed to engineer around the patent by using a different mechanism for sorting viable from nonviable cells called elutriation, though the effectiveness of that method -- and perhaps of other alternatives -- is subject to dispute in LTC's damages motion (see LTC's Resp. to Celsis' LR 56.1 St. ¶ 6 on the damages issue, Dkt. 409). In any event Univ. of Utah, 774 F.3d at 764 n.4 recently reasoned that the "preemptive nature of the claims" at issue in that case was "not ameliorated" by virtue of the fact that there might have been other routine ways to get around the

patent -- if patent law were to permit a lock on a narrow albeit routine combination of steps, "different combinations of other routine steps" (id.) would also be patent-eligible.

Put another way, if one were allowed to own a slice of the preemptive pie, that would pave the way for multiple others to claim the rest of that pie. Such a result would clearly run counter to the teaching and purpose of Mayo and Alice. Hence this Court adopts the Univ. of Utah reasoning here.[8]

Patent Validity Under Section 112

Section 112(b) requires that a patent specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." Until recently a patent satisfied that definiteness requirement before the Federal Circuit so long as it was not "insolubly ambiguous" (Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014)). Last year Nautilus, id. (emphasis added) replaced that standard with a less lenient one under which "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." That standard "mandates clarity, while recognizing that absolute precision is unattainable" (id. at 2129) -- and "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter" (id., quoted from Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270 (1916)). Importantly, indefiniteness must be assessed from the perspective of someone skilled in the art at the time of the patent filing (id. at 2128).

[8] See also 1 Donald Chisum, Chisum on Patents § 1.03[2][f] at 1-138.27 (2014), noting that Alice's two-part test does not separately require courts to examine whether the patent disproportionately ties up a law of nature.

LTC also argues that the '929 Patent is indefinite as a matter of law because the Trypan Blue Exclusion method is so inherently variable, varying as much as 50%. Celsis counters that the variance is some 15% or less and that, because it is the standard industry test -- used even by LTC -- it cannot possibly fail to inform those skilled in the art of the metes and bounds of the patent "with reasonable certainty." Although it seems that Celsis has the better of it at the summary judgment stage (each of the cases sought to be relied on by LTC is inapposite), the Section 112(b) issue need not be addressed (let alone resolved). What has gone before has dispatched the '929 Patent under Section 101, and that is enough.

Conclusion

Because the patent is invalid under Section 101, this Court grants LTC's Motion for Summary Judgment of Patent Invalidity (Dkt. 335). That causes LTC's Motion To Limit Damages to a Reasonable Royalty on LTC's Accused Sales (Dkt. 337) to be denied as moot.

Milton I. Shadur
Senior United States District Judge

Date: March 13, 2015